Distributor Letter (Accu-Chek Insight battery)

Urgent field safety notice

<Enter address here>

Location, Date

Important information on the Accu-Chek® Insight insulin pump system:
Update of the handling instructions to ensure usage of the appropriate batteries and optimal battery lifetime

Dear Distributor / Retailer [*please personalize*],

We recently received feedback from a limited number of people with diabetes using the Accu-Chek Insight insulin pump system that they are experiencing a rapid power drop or a system shut off due to battery issues. We have thoroughly investigated these cases and identified low-quality batteries or an incorrectly selected battery type setting on the pump to be the root cause of such battery issues. Using the high-quality batteries described below and selecting the correct battery type will prevent the future occurrence of this issue. We sincerely apologize for any inconvenience this may have caused you and your customers and hope the enhanced handling information provided with this communication supports your customers in a safe, reliable and satisfactory use of the Accu-Chek Insight insulin pump system.

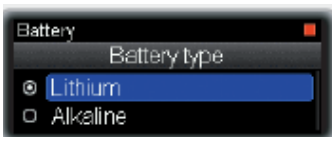
Recommended actions to be taken:

1. Based on our investigation results, we recommend the following high-quality batteries for use with the Accu-Chek Insight system:

   Lithium battery
   Use only lithium batteries that comply with IEC 60086-4 as e.g."Energizer® Ultimate Lithium, FR03, 1.5V AAA (FR03)". These have been successfully tested with the Accu-Chek Insight insulin pump.

   Alkaline battery
   Use only high-quality alkaline batteries (1.5V AAA (LR03)) that are suitable for energy-intensive devices, such as those requiring a flash. This is shown by a "Flash"symbol on the packaging (see picture).

2. **Please advise your customers to not use** carbon zinc or rechargeable nickel cadmium (NiCd/NiMH) batteries with the Accu-Chek Insight insulin pump.
3. **Please also advise your customers to make sure to always confirm the correct battery type** on the insulin pump upon the battery change.



If users follow the battery recommendation and handling instruction provided with this communication the pump will work safely and reliable for up to 30 days with a new high-quality lithium battery, if used as directed.

What are the risks using low-quality batteries and/or selecting the incorrect battery type:
Using low-quality batteries may lead to a risk of the battery having a very short lifetime of only a few days and a sudden power drop which may cause an unexpected shut down of the insulin pump. In some cases, the pump might not even give an alarm due to a very rapid voltage drop. Using the recommended batteries will enable a clear and early detection and remind the user to change the battery.. Such an undetected sudden shut off of the insulin pump potentially could result in an underdelivery of insulin, particularly during night-time.

Selecting the incorrect battery type on the insulin pump may impact the detection of the remaining voltage, which can also lead to the above described issues, as lithium and alkaline batteries have different type-specific characteristics

To avoid this risk it is key, to follow the battery recommendation and change the battery as described in the user manual of the Accu-Chek Insight system. As patient safety is our top priority, Roche Diabetes Care has started to further enhance its handling instructions for the Accu-Chek Insight system. With this we aim to ensure that every user of the Accu-Chek Insight insulin pump selects the appropriate batteries for the system. This would mitigate the risk of a sudden voltage drop or an unexpected shut off of the insulin pump.

If your customers however, experience such a rapid power drop, please advise them to contact our Accu-Chek Customer Care line at xxx-xxx-xxx. This issue is only affecting the Accu-Chek Insight system and the competent authority, healthcare professionals and users of the Accu-Chek Insight system have been informed about this field action. Please forward this information to all those who need to be aware within your organisation.

Thank you in advance for your understanding and co-operation. If you have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line at xxx-xxx-xxx or your local Accu-Chek sales representative at any time.

Kind regards,
Roche Diabetes Care

HCP Letter
(Accu-Chek Insight battery)

Urgent field safety notice

<Enter address here>

Location, Date

Important information on the Accu-Chek® Insight insulin pump system:
Update of the handling instructions to ensure usage of the appropriate batteries and optimal battery lifetime

Dear Healthcare Professional [*please personalize*],

We recently received feedback from a limited number of people with diabetes using the Accu-Chek Insight insulin pump system that they are experiencing a rapid power drop or a system shut off due to battery issues. We have thoroughly investigated these cases and identified low-quality batteries or an incorrectly selected battery type setting on the pump to be the root cause of such battery issues. Using the high-quality batteries described below and selecting the correct battery type will prevent the future occurrence of this issue. We sincerely apologize for any inconvenience this may have caused you and your patients and hope the enhanced handling information provided with this communication supports your patients in a safe, reliable and satisfactory use of the Accu-Chek Insight insulin pump system.

Recommended actions to be taken:

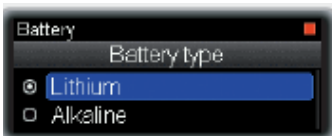
1. Based on our investigation results, we recommend the following high-quality batteries for use with the Accu-Chek Insight system:

   Lithium battery
   Use only lithium batteries that comply with IEC 60086-4 as e.g."Energizer® Ultimate Lithium, FR03, 1.5V AAA (FR03)". These have been successfully tested with the Accu-Chek Insight insulin pump.

   Alkaline battery
   Use only high-quality alkaline batteries (1.5V AAA (LR03)) that are suitable for energy-intensive devices, such as those requiring a flash. This is shown by a "Flash"symbol on the packaging (see picture).

2. **Please advise your patients not to use** carbon zinc or rechargeable nickel cadmium (NiCd/NiMH) batteries with the Accu-Chek Insight insulin pump.

3. **Please also train your patients to make sure to always confirm the correct battery type** on the insulin pump upon the battery change.



If users follow the battery recommendation and handling instruction provided with this communication the pump will work safely and reliable for up to 30 days with a new high-quality lithium battery, if used as directed.

What are the risks using low-quality batteries and/or selecting the incorrect battery type:
Using low-quality batteries may lead to a risk of the battery having a very short lifetime of only a few days and a sudden power drop which may cause an unexpected shut down of the insulin pump. In some cases, the pump might not even give an alarm due to a very rapid voltage drop. Using the recommended batteries will enable a clear and early detection and remind the user to change the battery. Such an undetected sudden shut off of the insulin pump potentially could result in an underdelivery of insulin, particularly during night-time.

Selecting the incorrect battery type on the insulin pump may impact the detection of the remaining voltage, which can also lead to the above described issues, as lithium and alkaline batteries have different type-specific characteristics

To avoid this risk it is key, to follow the battery recommendation and change the battery as described in the user manual of the Accu-Chek Insight system. As patient safety is our top priority, Roche Diabetes Care has started to further enhance its handling instructions for the Accu-Chek Insight system. With this we aim to ensure that every user of the Accu-Chek Insight insulin pump selects the appropriate batteries for the system. This would mitigate the risk of a sudden voltage drop or an unexpected shut off of the insulin pump.

If your patients however, experience such a rapid power drop, please advise them to contact our Accu-Chek Customer Care line at xxx-xxx-xxx. This issue is only affecting the Accu-Chek Insight system and the competent authority, distributors and users of the Accu-Chek Insight system have been informed about this field action. Please forward this information to all those who need to be aware within your organisation.

Thank you in advance for your understanding and co-operation. If you have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line at xxx-xxx-xxx or your local Accu-Chek sales representative at any time.

Kind regards,
Roche Diabetes Care

Consumer Letter (Accu-Chek Insight battery)

Urgent field safety notice

<Enter address here>

Location, Date

Important information on the Accu-Chek® Insight insulin pump:
Update of the handling instructions to ensure usage of the appropriate batteries and optimal battery lifetime

Dear Customer [*please personalize*],

We recently received feedback from a limited number of people with diabetes using the Accu-Chek Insight insulin pump system that they are experiencing a rapid power drop or a system shut off due to battery issues. We have thoroughly investigated these cases and identified low-quality batteries or an incorrectly selected battery type setting on the pump to be the root cause of such battery issues. Using the high-quality batteries described below and selecting the correct battery type will prevent the future occurrence of this issue. We sincerely apologize for any inconvenience this may have caused and hope that the enhanced handling information provided with this communication supports you in a safe, reliable and satisfactory use of your Accu-Chek Insight insulin pump system.

Recommended actions to be taken:

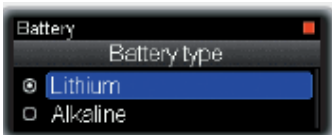
1. Based on our investigation results, we recommend the following high-quality batteries for use with the Accu-Chek Insight system:

   Lithium battery
   Use only lithium batteries that comply with IEC 60086-4 as e.g."Energizer® Ultimate Lithium, FR03, 1.5V AAA (FR03)". These have been successfully tested with the Accu-Chek Insight insulin pump.

   Alkaline battery
   Use only high-quality alkaline batteries (1.5V AAA (LR03)) that are suitable for energy-intensive devices, such as those requiring a flash. This is shown by a “Flash”symbol on the packaging (see picture).

2. Please **do not use** carbon zinc or rechargeable nickel cadmium (NiCd/NiMH) batteries with your Accu-Chek Insight insulin pump.

3. Please make sure that you **always confirm the correct battery type** on your insulin pump upon the battery change.



If you follow the battery recommendation and handling instruction provided with this communication your pump will work safely and reliable for up to 30 days with a new high-quality lithium battery, if used as directed.

What are the risks using low-quality batteries and/or selecting the incorrect battery type:
Using low-quality batteries may lead to a risk of the battery having a very short lifetime of only a few days and a sudden power drop which may cause an unexpected shut down of the insulin pump. In some cases, the pump might not even give an alarm due to a very rapid voltage drop. Using the recommended batteries will enable a clear and early detection and remind the user to change the battery. Such an undetected sudden shut off of the insulin pump potentially could result in an underdelivery of insulin, particularly during night-time.

Selecting the incorrect battery type on the insulin pump may impact the detection of the remaining voltage, which can also lead to the above described issues, as lithium and alkaline batteries have different type-specific characteristics

To avoid these risks it is key, to follow the battery recommendation and change the battery as described in the user manual of the Accu-Chek Insight system. As patient safety is our top priority, Roche Diabetes Care has started to further enhance its handling instructions for the Accu-Chek Insight system. With this we aim to ensure that every user of the Accu-Chek Insight insulin pump selects the appropriate batteries for the system. This would mitigate the risk of a sudden voltage drop or an unexpected shut off of the insulin pump.

If you however, experience such a rapid power drop, please contact our Accu-Chek Customer Care line at xxx-xxx-xxx. This issue is only affecting the Accu-Chek Insight system and the competent authority, distributors and healthcare professionals have been informed about this field action.

Thank you in advance for your understanding and co-operation. If you have any further questions, please do not hesitate to contact our Accu-Chek Customer Care line at xxx-xxx-xxx or your local Accu-Chek sales representative at any time.

Kind regards,
Roche Diabetes Care